

**REMARKS/ARGUMENTS**

Claims 2-13, 18-30, 33-41, and 51-60 remain in this application. Claims 28, 29, 33, 35, 37, and 52 were amended above. Claim 31 was canceled above. New claims 55-60 were added to further define the process of claims 35 and 51. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned  
**“Version with marking to show changes made.”**

The Final Office Action rejected the claims under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner et al (U.S.P.N. 5,252,484) and further in view of Shalaby et al (U.S.P.N. 5,422,068), Dunn et al (U.S.P.N. 4,910,942), and Heyl et al (U.S.P.N. 5,431,879). Applicants mailed an Amendment After Final on May 29, 2002 responsive to those rejections.

An Advisory Action was mailed July 17, 2002. The Advisory Action stated that Applicants' Amendment After Final did "NOT place the application in condition for allowance because: In the office action dated 01/29/2002, page 3, I referred to figure 8 with respect to the concept of a contact lens package receiving radiation from substantially all directions. I should not have referred to this figure. Although such a figure deal with one type of embodiment for holding contact lens, I meant to refer to figure 1, wherein package 12 is made of material which will transmit in all directions and capable of holding contact lens. See col. 6, lines 63-67 and col. 7, lines 1-3. In col. 7, lines 1-3, Clark states that contact lens packages can be used in the apparatus of figure 1. Then Clark goes on to further show that various materials can be used to design product packages including a contact lens container which can be used in the apparatus of figure 1. See col. 7, lines 3-12." Advisory Action, page 2.

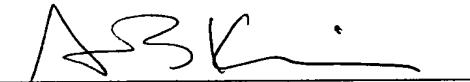
Applicants traverse this rejection. Although it is true that at col. 6, lines 63-67 and col. 7, lines 1-3, Clark et al state that a contact lens can be treated by the method shown in Figure 1, Clark et al do not teach nor suggest that the contact lens container can or should be transmissive to radiation in substantially all directions as Applicants have claimed in claim 51, and therefore all the dependent claims too. It was known at the time Clark et al was filed that contact lens packaging typically consisted of a thermoplastic bowl and a foil lid, and yet Clark et al follow

the statement at col. 7, lines 1-3: "For example, contact lens packages and the contact lens contained therein can be treated using the above-approach [of Figure 1]." with the statement: "As a result, materials such as Olefins, nylon, and composite materials may advantageously be employed in product packages, instead of more conventional materials, such as polyvinyl chloride (PVC). Clark et al, therefore, does not teach or suggest or provide any motivation for modifying contact lens packages to modify the foil lidstock to provide for transmissivity in substantially all directions. Perhaps Clark et al provide motivation to change the thermoplastic blister material, but not the foil lidstock.

Additionally, Figures 3-6 of Clark et al show contact lens packages having a blister and a foil backing 58 (col. 7, line 67; col. 8, line 2; and col. 8, line 31). At col. 8, line 40, col. 8, lines 49-50 and col. 8, line 60, Clark et al state that the blisters shown in Figures 4-6 are suitable for treatment in Figure 1, yet the arrows in Figures 4 and 6 are shown directed only at the blisters. Therefore, Clark et al do not provide any teaching or suggestion to modify a contact lens package to provide for transmissivity in substantially all directions as Applicants have claimed. Additionally, Clark et al provide no motivation to do as Applicants have, because Clark et al teach and show radiation penetrating only the blister of a contact lens package and state that the method can be used to provide sterilization (col. 8, line 33). Applicants determined that in their method of sterilization, the contact lens container had to provide transmissivity in substantially all directions to provide sterilization. Because Clark et al do not teach nor suggest Applicants' claimed method, Clark et al is insufficient, either alone or in combination with the other cited references, for all the reasons herein and in the previously filed Amendments and Response to establish a *prima facie* case of obviousness. It is therefore respectfully requested that the rejections of the claims be withdrawn and that claims 2-13, 18-30, 33-41, and 51-56 be allowed to issue as a patent.

Early allowance is respectfully solicited. If for any reason the Examiner believes the claims are not in proper condition for allowance, a telephone interview with the Applicants' attorney, named below, would be appreciated.

Respectfully submitted,

By:   
Anne B. Kiernan  
Reg. No. 36,566

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2724  
Dated: September 9, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADEIn the Claims:

**Claims 28, 29, 33, 35, 37, and 52 were amended as follows:**

28. (Amended twice) The process of claim 20, wherein prior to said subjecting step is the step of modifying radiation from a radiation source to eliminate wavelengths which would damage said [medical device] contact lens.

29. (Amended twice) The process of claim 21, wherein said minimum total energy density of said ultraviolet radiation in the range of 240 to 280 nm which reaches said microorganisms, further reaches said contents of said container whereby the entire contents of said container and said [medical device] contact lens are sterilized.

33. (Amended twice) The process of claim 51 wherein said container comprises a lid and a bowl, wherein said lid and said bowl [comprise] consist essentially of thermoplastics and said lid and said bowl are transmissive to at least 50% of said radiation in the range of 240 to 280 nm in substantially all directions.

35. (Amended twice) The process of claim [34] 51 wherein said subjecting step follows the steps of:

- (a) forming a contact lens;
- (b) placing said contact lens in a container; and
- (c) moving said container into an apparatus comprising a radiation source; and

wherein said apparatus is light-tight during said subjecting step.

37. (Amended twice) The process of claim 35 wherein said [medical device] comprises a] contact lens comprises[ing] UV-blocker which blocks greater than 50 % of the radiation in the range of 240 to 280 nm.

**RECEIVED**

SEP 19 2002

TC 1700

52. (Amended once) The process of claim 51 wherein said subjecting step further provides:

subjecting said [medical device] contact lens to ultraviolet radiation whereby the  $D_{value}$  of Bacillus stearothermophilus, ATCC 7953, is at least 3.9 mJ/cm<sup>2</sup> ultraviolet radiation in the range of 240 to 280 nm to the spore.

**Claim 31 was canceled as follows:**

[31. The process of claim 30 wherein said container is transmissive to at least 50 % of said ultraviolet radiation in the range of 240 to 280 nm].

**New claims 55, 56, 57, 58, 59 and 60 were added as follows:**

--55. The process of claim 51, wherein during said subjecting step said container is within an apparatus comprising a radiation source and said apparatus is light-tight during said subjecting step.

56. The process of claim 33, wherein during said subjecting step said container is within an apparatus comprising a radiation source and said apparatus is light-tight during said subjecting step.

57. The process of claim 35, wherein said apparatus comprises:  
at least one radiation source and at least one reflector wherein at least one said reflector directs radiation from said radiation source to a treatment area, such that at least 3 J/cm<sup>2</sup> broad spectrum radiation of which at least 50 mJ/cm<sup>2</sup> of said radiation is UV radiation in the range of 240 to 280 nm reaches said treatment area, said treatment area is located at the focal plane of said at least one reflector, and further said treatment area is where said container is placed to receive the radiation wherein said apparatus further comprises a power supply which has a capacitance of 80 to 160 microFarad.

58. The process of claim 57 further comprising a power supply which can generate a potential of 2500-6000 volts.

59. The process of claim 57 wherein said at least one reflector has enhanced reflection in the ultraviolet.

60. The process of claim 57 wherein said at least one reflector minimizes the non-ultraviolet radiation reaching said contact lens.--